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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,679

03/18/2004

Andrew D. Sutton

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09/27/2006

MORRISON & FOERSTER LLP

755 PAGE MILL RD

PALO ALTO, CA 94304-1018

EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,679

Applicant(s)

SUTTON ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22-24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 20, 22-24 and 26-31 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on March 3, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. In response to office action, applicants cite several applications in which the instant invention is a continuation of. However, the specification states that the instant invention is a CIP of 07/956,875. If what is stated in the response with respect to continuing data, this needs to be inserted in the first line of the specification.

Action Summary

4. Examiner acknowledges the cancellation of claims 21 and 25. Therefore, any and all objections and/or rejections directed towards them are hereby withdrawn.

Art Unit: 1616

5. The rejection of claims 10, 26 and 27 under the judicially created doctrine of obviousness-type double patenting over claims 1 and 13 of US 6,709,650 is hereby withdrawn as applicants have amended the claim to overcome the rejection.

6. The rejection of claims 20, 22-23 and 26-28 under 35 U.S.C. 102(e) as being anticipated by Platz et al. is being maintained for the reasons stated in the previous office action. The office action will be repeated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 20, 22-23 and 26-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Platz et al. (US 6,509,006 B1).

Platz et al. discloses a pharmaceutical-based dry powder composition for pulmonary delivery, wherein the composition comprises a therapeutically effective amount of a pharmaceutical in combination with a pharmaceutically acceptable carrier (col. 5, lines 63-67). Column 8 line 67 through column 9, lines 1-7 teach the preferred particle size as being less than 10 microns. Column 9, lines 1-13 teach the pharmaceutical as a protein, peptide or enzyme. Column 6, lines 27-34 teach the

Art Unit: 1616

carrier in amounts from 0.05% to 99.5%. Column 6, lines 35-67 through column 7, lines 1-6 teach the carrier as an excipient such as bulking agents for example carbohydrates, polysaccharides, mannitol, etc. Column 7, lines 27-56 teach a dry powder inhaler for the composition.

Response to Arguments

8. Applicant's arguments filed February 28, 2006 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference of Platz et al. does not qualify as prior art under 35 U.S.C. 102(e) using the filing date of July 8, 1992 of Application No. 07/910,048 because the material disclosed in the prior art is not supported in '048. Examiner disagrees. Platz et al. qualifies as prior art against the instant invention. In a review of the Patent No. 5,458,135 (07/910,048) listed in Platz et al. it was determined that support for the material in the patent (Platz et al.) is found in col. 5, lines 52-59, which teach delivering medicaments, drugs, etc. to the lung wherein the medicament can be proteins and polypeptides. Column 6, lines 6-9 teach the end particle size to be predominantly 1 to 5 microns. Thus the instant invention remains anticipated by the prior art and as such claims newly added claims 29-31 are also rejected.

Claim Objections

9. Claims 22, 23, 26 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous

Art Unit: 1616

claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 22, 23, 26 are object to for depending from cancelled claims and claim 27 is objected too for depending on claim 36.

Conclusion

10. Claims 20, 22-23 and 26-31 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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